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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/818,534	03/14/97	NELSON	W 3922

EXAMINER

HM12/0205

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ART UNIT	PAPER NUMBER
1645	23

DATE MAILED: 02/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/818,534	Nels n et al.
Examiner	**Group Art Unit**
Ja-Na Hines	1645

☒ Responsive to communication(s) filed on *Nov 20, 2000*

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *2 and 9-12* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *2 and 9-12* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Amendment Entry

1. Amendments have been entered as filed on November 20, 2000. Claims 9 and 12 have been amended. Claims 2 and 9-12 are pending in this office action.

Drawings

2. Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect can be deferred until the application is allowed by the examiner.

Response to Arguments

3. Applicant's arguments filed November 20, 2000 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 2, 9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al. (US 4,487,198) in view of Herron et al., is maintained.

Applicants argues that the cited combined references fail to teach or suggest a method for detecting the presence of a specific microorganism in a sample, wherein the antibodies emit essentially no resonance Raman spectra that interfere with the resonance Raman spectra of the microorganism. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, Applicant use antibodies for the same purpose, i.e., immobilization and achieves the same results, Raman spectra analysis, as the prior art references, therefore no more then routine skill would have been required. No more then routine skill have been required at the time of applicants' invention to have used capture molecules like antibodies immobilized to a solid phase which specifically bind in antibody-antigen complex where the antigen or analyte is a microorganism as taught by Herron et al., in conjunction with a method for detecting the presence of a specific microorganism in a sample without interference to the energy spectra as taught by

Nelson et al., because Herron et al., teaches immobilizing bacteria using antibodies is well known in the art as a method of immobilization.

5. Claims 2 and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chadha et al., in view of Herron et al., is maintained.

In response to applicant's argument that there is no suggestion to combine the references, because the cited combined references fail to teach or suggest a method for detecting the presence of a specific microorganism in a sample, wherein the antibodies emit essentially no resonance Raman spectra that interfere with the resonance Raman spectra of the microorganism.
The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, no more then routine skill is required to substitute biospecific antibodies for the disclosed polylysine, because biospecific antibodies are conventionally used to immobilize bacteria analytes for assay. Chadha et al., teaches that resonance Raman spectra of a number of bacteria and bacterial spores, excited at 200-257nm have been reported.."(page 3089 para. 2). "With 242, 252, 257nm excitation, vibrational modes of various nucleosides, nucleic acids,

quinones, and calcium dipicolinate are selectively excited.."(page 3089 para. 2). "Nucleic acids have a prominent absorption band around 260 nm, consequently it is not surprising Raman spectra with 257 nm excitation would contain several strong resonance enhanced vibrational modes due to nucleic acids." (page 3092 para. 3). Further Chadha et al., teaches the benefits of washing cells and for using nucleic acids as markers because they show strong resonance enhanced vibrational modes and provided better signals over the interference in Raman spectroscopy. The instant application states a wavelength range between 242-257nm, however Chadha et al., teaches the benefits for using 242nm (because it promises better signal to noise even if Raman cross sections are lower) and 257nm (because it would contain several strong resonance enhanced vibrational modes due to nucleic acids) and that the wavelengths of 242, 252, 257nm are selectively excited for the vibrational modes of various nucleosides and nucleic acids.

Accordingly there would have been a reasonable expectation of success for one skilled in the art to modify the method and system of Chadha et al., by substituting the immobilization of antibody to a solid phase because the specificity of antibodies are conventionally used to bind and immobilize bacterial antigens for an assay as taught by Herron et al., without obscuring the Raman spectra energy.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines

January 30, 2001

1/31/01

JENNIFER GRASER
PATENT EXAMINER